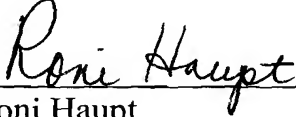


PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. :	10/799,297)	CERTIFICATE OF EFS WEB FILING
Applicant :	Donald E. Brodnick)	
Filed :	03/12/2004)	I hereby certify that this correspondence
Title :	Respiration Monitoring System And Method)	is being electronically filed on this 4 th
TC/A.U. :	3735)	day of September, 2007.
Examiner :	Karen E. Toth)	
Docket No. :	139341-1 (5024-00079))	
Confirmation No.	8184)	

	9-4-07
Roni Haupt	Date

AMENDMENT

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper responds to an Office Action mailed June 1, 2007. The three month response deadline expired on September 1, 2007, which was a Saturday. The extended three month deadline is September 4, 2007. Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 9 of this paper.

Listing of Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A patient monitoring system comprising:
a plurality of inputs, the plurality of inputs being configured to be coupled to a plurality of electrodes including first, second and third electrodes;
a processing circuit coupled to the plurality of inputs, the processing circuit being configured to process signals from the plurality of electrodes to produce a respiration parameter for a patient, the processing circuit having a first mode of operation in which the processing circuit produces the respiration parameter by measuring impedance between the first and second electrodes and uses the third electrode to eliminate or reduce a common mode voltage present in the signals obtained from the first and second electrodes, and the processing circuit having a second mode of operation in which the processing circuit produces the respiration parameter by measuring impedance between the third electrode and an additional one of the plurality of electrodes.
2. (Original) The system of claim 1, wherein the third electrode is connected to the processing circuit by the RL leadwire
3. (Original) The system of claim 1, wherein the processing circuit is capable of operating in the first and second modes of operation simultaneously.
4. (Original) The system of claim 1, wherein the additional one of the plurality of electrodes is one of the first and second electrodes.
5. (Original) The system of claim 1, wherein the respiration parameter is respiration rate.

6. (Original) The system of claim 1, wherein the first and second electrodes are attached to a human having a abdomen and at least one lung and further wherein the first electrode and second electrodes are attached to the human such that a straight line extending from the first electrode to the second electrode passes through a lower portion of the lungs adjacent to the abdomen.
7. (Original) The system of claim 6, wherein the straight line substantially avoids passing through an aorta, heart, neck, or any shoulder of the patient.
8. (Original) The system of claim 6, wherein the first electrode is attached to at least a right or left leg.
9. (Original) The system of claim 8, wherein the first electrode is attached to the left leg at a LL location or to the right leg at a RL location.
10. (Original) The system of claim 6, wherein the second electrode is attached to an opposite side of abdomen as the first electrode and further wherein the second electrode is located below an armpit.
11. (Original) The system of claim 1, wherein the second electrode is attached to an electrode location selected from the group consisting of the V5R, HV5R, V6R, HV6R, V5, HV5, V6, and HV6 electrode locations.
12. (Original) The system of claim 11, wherein the second electrode is attached to an electrode location selected from the group consisting of the V5R V6R, HV5R and HV6R electrode locations.

13. (Currently amended) An apparatus for monitoring the respiration rate of a human having a thorax and at least one lung, the apparatus comprising:

a first input configured to be connected to a first electrode attached to the thorax;

a second input configured to be connected to a second electrode attached to an opposite side of the thorax as the first electrode, and such that a first conductive path extends through a lower portion of the lungs between the first and second ~~electrodes~~inputs;

a third input configured to be connected to a third electrode, the third electrode being a RL electrode that is configured to both eliminate or reduce a common mode voltage present in signals obtained from the first and second electrodes and provide a second conductive path with one of the first or second electrodes; and

a processing circuit configured to detect fluctuations in impedance in the first or second conductive paths, and derive a respiration signal at least from the fluctuations.

14. (Original) The apparatus of claim 13, wherein the processing circuit is also an ECG monitoring circuit that is configured to use a signal from the third electrode as a voltage reference signal in the ECG monitoring circuit.

15. (Original) The apparatus of claim 13, wherein the processing circuit is configured to be coupled to the first electrode to at least a right or a left leg.

16. (Original) The apparatus of claim 15, wherein the processing circuit is configured to be coupled to the first electrode at the LL location or to the right leg at the RL location.

17. (Original) The apparatus of claim 13, wherein the processing circuit is configured to be coupled to the second electrode at the opposite side of thorax below the armpit.

18. (Original) The apparatus of claim 12, wherein the processing circuit is configured

to be coupled to the second electrode at an electrode location selected from the group consisting of the V5R, HV5R, V6R, HV6R, V5, HV5, V6, and HV6 electrode locations.

19. (Original) The apparatus of claim 18, wherein the processing circuit is configured to be coupled to the second electrode at an electrode location selected from the group consisting of the V5R, HV5R, V6R, and HV6R electrode locations.

20. (Original) The apparatus of claim 13, wherein the processing circuit includes an electronic display screen, and further wherein the processing circuit is configured to display the respiration signal on the electronic display screen as a respiration rate numeric value.

21. (Original) The apparatus of claim 20, wherein the processing circuit is configured to display the respiration signal as a trace.

22. (Original) The apparatus of claim 21, wherein the processing circuit is configured to display the trace on the electronic display screen.

23. (Cancelled)

24. (Original) A patient monitor comprising:
an operator input device;
a plurality of signal inputs, the plurality of signal inputs being configured to receive signals from electrodes attached to a patient;
a processing circuit, the processing circuit being configured to process the signals received from the electrodes to generate a Lead I signal, a Lead II signal, and an abdominal respiration lead signal;

a display, the display being configured to display options for selection by the operator using the operator input device, the options including an option to display a parameter associated with the abdominal respiration lead signal.

25. (Original) A method of monitoring the respiration rate of a human having an abdomen and at least one lung, the method comprising the steps of:

detecting fluctuations in impedance in a conductive path between first and second electrodes and using a third electrode to eliminate or reduce a common mode voltage present in signals obtained from the first and second electrode in a first mode of operation of a processing circuit, the first electrode and second electrode being attached to the human such that a straight line extending from the first electrode to the second electrode passes through a lower portion of the lungs adjacent to the abdomen;

detecting fluctuations in impedance in a conductive path between the third electrode and one of the first and second electrodes in a second mode of operation of the processing circuit; and

deriving a respiration parameter based at least on the fluctuations.

26. (Original) A system for monitoring the respiration rate of a human having a thorax and at least one lung, the apparatus comprising:

a first electrode means for sensing body impedance, the first electrode being configured to be fixed to the thorax on the left leg at a LL location or on the right leg at a RL location;

a second electrode means for sensing body impedance and configured to be fixed below the armpit on to an opposite side of the thorax as the first electrode means for sensing body impedance to thereby define a conductive path extending through a lower portion of the lungs between the first and second electrodes means for sensing impedance;

a third electrode ~~means~~ for eliminating or reducing a common mode voltage present in signals obtained from the first and second means, ~~the third means being a RL electrode~~; and

a means for monitoring respiration configured to detect fluctuations in impedance in the conductive path, and to derive a respiration signal at least from said fluctuations, said monitoring means being coupled to the first and second electrodes ~~means for sensing~~ and coupled via the electrodes ~~means for sensing~~ to the human.

27. (Currently amended) The system of claim 26, wherein the monitoring means is an ECG monitoring circuit that is configured to use a signal from the third electrode ~~means~~ for sensing as a voltage reference signal in the ECG monitoring circuit.

28. (Cancelled)

29. (Cancelled)

30. (Cancelled)

31. (Currently amended) The system of claim 26, wherein the monitoring means is configured to be coupled to the second electrode ~~means for sensing~~ at an electrode location selected from the group consisting of the V5R, HV5R, V6R, HV6R, V5, HV5, V6, and HV6 electrode locations.

32. (Currently amended) The system of claim 31, wherein the monitoring means is configured to be coupled to the second electrode ~~means for sensing~~ at an electrode location selected from the group consisting of the V5R, HV5R, V6R, and HV6R electrode locations.

33. (Original) The system of claim 26, wherein the monitoring means includes an electronic display screen, and further wherein the monitoring means is configured to display the respiration signal on the electronic display screen as a respiration rate numeric value.

34. (Original) The system of claim 33, wherein the monitoring means is configured to display the respiration signal as a trace.

35. (Original) The system of claim 34, wherein the monitoring means is configured to display the trace on the electronic display screen.

36. (Original) The system of claim 26 further comprising a hospital information system, and wherein the monitoring means is coupled to the hospital information system to make information derived from the respiration signal available on the hospital information system.

REMARKS

In the Office Action, the Examiner initially objected to the oath or declaration originally filed by the applicant. Specifically, the Examiner indicated that the original oath included the statement that the applicant acknowledged a duty to disclose information “material to the examination” when the declaration required the phrase to state that information is being disclosed that is “material to patentability”. A substitute declaration executed by both of the inventors indicating that the information submitted to the USPTO was all the information known by the inventors to be “material to patentability” is submitted herewith.

In the Office Action, the Examiner indicated that claim 1-12, 18, 19, 24 and 25 were allowed over the prior art identified by the Examiner. The applicant hereby acknowledges and appreciates such finding by the Examiner.

In the Office Action, claim 23 was rejected under 35 USC §102(b) as being anticipated by the Kearns U.S. Patent No. 4,387,722. By the present response, claim 23 has been cancelled from the present application such that the rejection under §102(b) has been rendered moot.

In the Office Action, claims 13-17, 20-22 and 26-35 were rejected under 35 USC §103(a) as being anticipated by the Kearns ‘722 patent in combination with the Rohde U.S. Patent No. 5,876,351. The applicant assumes the Examiner intended to reject these claims based upon the combination of the Kearns ‘722 and Rohde ‘351 references under §103, rather than §102(b) as set forth on page 3 of the Office Action.

Reconsideration of the above claim rejections is respectfully requested in view of the foregoing claim amendments, as well as the following arguments for allowance.

Claim 13

By the present response, independent claim 13 has been amended to indicate that the apparatus includes a third electrode that is configured to both eliminate or reduce a common mode voltage present in signals obtained from the first and second electrodes

and to provide a second conductive path with one of the first and second electrodes.

Claim 13 has also been amended to indicate that the processing circuit is configured to detect fluctuations and impedance in the first or second conductive path and to derive a respiration signal from the fluctuation.

In the reasons for allowance included in the outstanding Office Action, the Examiner indicated that the second conductive path between one of the first and second electrodes and the third electrode was not taught or suggested by any of the references cited by the Examiner. Based upon these comments made by the Examiner in the Office Action and the amendments made to claim 13, independent claim 13 is now believed to be in condition for allowance.

Claims 14-17, 20-22 depend directly or indirectly from claim 13 and are thus also believed to be allowable.

Claim 26

By the present response, independent claim 26 has been amended to indicate that the first electrode is configured to be fixed onto the thorax of a human on the left leg at the LL location or on the right leg at the RL location. Further, claim 26 requires the second electrode to be fixed below the armpit on an opposite side of the thorax as the first electrode for sensing body impedance and to thereby define a conductive path extending through a lower portion of the lungs between the first and second electrodes for sensing impedance. Claim 26 further requires a means for monitoring respiration that is configured to detect fluctuations in impedance in the conductive path between the first and second electrodes. This amendment generally combines the subject matter of original claims 26, 28, 29 and 30.

As taught in the specification of the present application, the position of the first and second electrodes is selected as described such that the conductive path extends across the thorax and through a lower portion of the lungs. This impedance path is particularly desirable to monitor the respiration rate of a patient when the patient is using

abdominal breathing, such as when the patient is unconscious. Since the conductive path passes over the lower portion of the lungs, this conductive path is an improvement over prior sensing techniques that utilize electrode placement across the upper portion of a patient's lungs.

In the Kearns '722 reference cited by the Examiner, the disclosure teaches the bipolar configuration of a set of electrodes E1 and E2 where each of the electrodes are placed over the sixth intercostals space on opposite sides of the thorax. (See col. 13, lines 29-43.) Although the electrodes E1 and E2 are positioned generally beneath the armpit over the six intercostals space, these electrodes are generally aligned with each other on opposite sides of the thorax. Thus, the first and second electrodes in the Kearns '722 reference do not teach a conductive path that extends through a lower portion of the lungs, as is required by claim 26. Specifically, claim 26 requires the first electrode to be fixed to the thorax on either the left leg or the right leg and the second electrode to be fixed generally below the armpit on the opposite side of the thorax. Clearly, the Kearns reference does not teach this location of the first and second electrodes or the conductive path created by the placement of these electrodes.

In rejecting claims 28-30, which have generally been incorporated into claim 26, the Examiner relied upon the Rohde '351 reference to show that a means for sensing may be connected to the patient's leg. As the Examiner correctly indicated, the placement of an ECG electrode on the patient's right or left leg is well known to one of ordinary skill in the art. However, independent claim 26 requires the placement of the first electrode on the right or left leg of the patient to be part of a conductive path that is utilized for monitoring the respiration rate of a human. The positioning of one of the two electrodes that defines the conductive path for sensing body impedance to monitor respiration rate on the leg is not taught or suggested by either the Rohde '351 or Kearns '722 references relied upon by the Examiner.

As described previously, the Kearns '722 reference teaches that both of the electrodes E1 and E2 are disposed over the sixth intercostals space. Thus, both the E1

and E2 electrodes are positioned under the armpits on the thorax. There is no teaching or suggestion in the Kearns '722 reference of utilizing the left leg location or the right leg location as part of the conductive path for respiration rate monitoring. Instead, the Kearns '722 reference teaches what is the known measurement option, namely positioning the first and second electrodes across the chest of the patient, as described in ¶ [0006] of the present application.

Likewise, although the Rohde '351 reference shows positioning an ECG electrode on one leg of a patient, there is no teaching or suggestion of utilizing an electrode placed on a leg of a patient to define one half of a conductive path that is utilized for monitoring the respiration rate of a human, as is required by claim 26.

Since neither of the references cited by the Examiner, either alone or in combination, teach the specific positioning of the first and second electrodes to define the conductive path as required by claim 26, independent claim 26 is allowable over the combination of references cited.

Claims 27, 31-36 depend directly or indirectly from claim 26 and are also believed to be allowable based upon the above arguments for allowance, as well as in view of the subject matter of each claim.

Conclusion

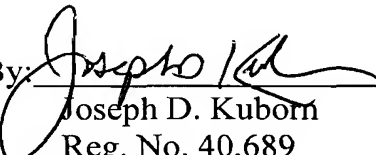
Based upon the Examiner's previous comments in the Office Action, claims 1-12, 18, 19, 24 and 25 have been allowed. Based upon the above arguments for allowance and claim amendments, claims 13-17, 20-22, 26-27 and 31-36 are also believed to be in condition for allowance.

Application No. 10/799,297
Amendment Dated September 4, 2007
Reply to Office Action of June 1, 2007

The Examiner is invited to contact the applicant's undersigned attorney with any questions or comments, or to otherwise facilitate prosecution of the present application.

Respectfully submitted,

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Reg. No. 40,689

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**DECLARATION FOR UTILITY OR
DESIGN
PATENT APPLICATION
(37 CFR 1.63)**

☐

Declaration
Submitted
With Initial
Filing

OR

☐

Declaration
Submitted after Initial
Filing (surcharge
(37 CFR 1.16 (e))
required)

Attorney Docket
Number

139341-1 (5024-00079)

First Named Inventor

Donald E. Brodnick

COMPLETE IF KNOWN

Application Number

10/799,297

Filing Date

03/12/2004

Art Unit

3735

Examiner Name

Karen E. Toth

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

RESPIRATION MONITORING SYSTEM AND METHOD

(Title of the Invention)

the specification of which

☐

is attached hereto

OR

☒

was filed on (MM/DD/YYYY)

03/24/2004

as United States Application Number or PCT International

Application Number

10/799,297

and was amended on (MM/DD/YYYY)

(if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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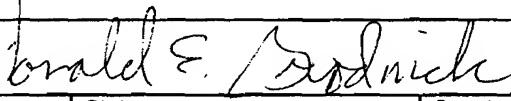
Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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DECLARATION — Utility or Design Patent Application

Direct all correspondence to: <input checked="" type="checkbox"/> The address associated with Customer Number:		73387	OR <input type="checkbox"/> Correspondence address below	
Name Joseph D. Kuborn				
Address 100 East Wisconsin Avenue, Suite 1100				
City Milwaukee		State Wisconsin		ZIP 53202
Country United States		Telephone 414-271-7590		Email
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NAME OF SOLE OR FIRST INVENTOR:		<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle [if any]) Donald E.		Family Name or Surname Brodnick		
Inventor's Signature 				Date 30-Aug-07
Residence: City Cedarburg		State WI		Country US
Mailing Address N75 W7115 Linden Street		Citizenship US		
City Cedarburg		State WI		Zip 53012
		Country USA		
<input checked="" type="checkbox"/> Additional inventors or a legal representative are being named on the 1 supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.				

PTO/SB/02A (07-07)

Approved for use through 08/30/2010. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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DECLARATION**ADDITIONAL INVENTOR(S)**
Supplemental Sheet

Page 2 of 2

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Scott R		Wiese	
Inventor's Signature <i>Scott R Wiese</i>		Date: 9/4/07	
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Mailing Address			
Wauwatosa City	WI State	53213 Zip	US Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.83. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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